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10/667,848	09/22/2003	Edward F. Ikeguchi	MSI -203-US	1385

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EXAMINER	
RAJ, RAJIV J	

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4143	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,848	IKEGUCHI ET AL.	
	Examiner	Art Unit	
	RAJIV J. RAJ	4143	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *24 May 2007 and 20 September 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 22 September 2003.

2. Claims 1-24 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statements filed 20 September 2006 and 24 May 2007 have been considered. Initialed copies of the Form 1449 are enclosed herewith.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0099302) (hereinafter Bardy) in view of Pence et al. (US 5978751) (hereinafter Pence).

Claim 1

Bardy as shown, discloses the following limitations:

- *accessing a trial database containing trial data of subjects in a clinical trial; performing a statistical analysis on the accessed trial database*; (see at least Bardy [0009] "Select stored

and derived measures are analyzed and changes in patient condition are logged. The logged changes are compared to quantified indicator thresholds to detect findings of respiratory distress or reduced exercise capacity indicative of the two principal cardiovascular pathophysiological manifestations of congestive heart failure: elevated left ventricular end diastolic pressure and reduced cardiac output, respectively.")

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059] "A predicted measure value can be calculated and compared to the appropriate indicator threshold 129 for determining whether the particular measure has either exceeded an acceptable threshold rate of change or the absolute threshold limit.")

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the steps of accessing, performing and determining while the clinical trial is ongoing*. (see at least Pence Fig. 2 Items:50, 52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine *accessing a trial database containing trial data of subjects in a clinical trial; performing a statistical analysis on the accessed trial database* and *determining whether the result of the statistical analysis exceeds a predetermined threshold value*, as taught in Bardy, with the *determining whether the result of the statistical analysis exceeds a predetermined threshold value*, as taught in Pence, with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system. (see at least Bardy [0008])

Claim 2

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis*; (see at least Bardy [0048] "In addition, the feedback module 128

determines whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") 133, as further described below with reference to FIG. 16. The threshold stickiness 133 can prevent fickleness in diagnostic routines resulting from transient, non-trending and non-significant fluctuations in the various collected and derived measures in favor of more certainty in diagnosis.")

- *retrieving only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011] "A plurality of monitoring sets is retrieved from a database. Each monitoring set includes recorded measures that each relates to patient information and include either medical device measures or derived measures calculable therefrom. The medical device measures are recorded on a substantially continuous basis. A set of indicator thresholds is defined.")

Claim 3

The combination of Bardy/Pence discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *wherein if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then waiting for a predetermined time period prior to the repeating step* (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 1, as taught in Bardy/Pence *wherein if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then waiting for a predetermined time period prior to the repeating step*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 4

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitations:

- *producing a grouped database from the clinical database and the blinding database for statistical analysis, the grouped database grouping the study data according to the study group*. (see at least Bardy Fig.5 Items:26,27,125,129-133)
- *accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs*; (see at least Bardy [0009] "Select stored and derived measures are analyzed and changes in patient condition are logged. The logged changes are compared to quantified indicator thresholds to detect findings of respiratory distress or reduced exercise capacity indicative of the two principal cardiovascular pathophysiological manifestations of congestive heart failure: elevated left ventricular end diastolic pressure and reduced cardiac output, respectively.")

Claim 5

The combination of Bardy/Pence discloses all the limitations of Claim 4. Pence further discloses the following limitation:

- *wherein the grouped database is stored in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51 "the unit history record mentioned above, a single record is stored in a database on disk 11 of FIG. 1 for each disk drive or device. There is keyed access to this record, based on the unique device serial number.")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 4, as taught in Bardy/Pence, with *the grouped database is stored in a memory device that is inaccessible by any user*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure that the integrity of the database is maintained.

Claim 6

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *wherein the step of performing a statistical analysis is executed without locking the trial database* (see at least Bardy [0048] "the analysis module 131 analyzes the results from the comparison module 130, which are stored as a combined measures set 95 (not shown), to a set of indicator thresholds 129,")

Claim 7

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *reading a predefined criteria that defines the level of cleanliness of trial data required for analysis*; (see at least Bardy [0048] "In addition, the feedback module 128 determines whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") 133, as further described below with reference to FIG. 16. The threshold stickiness 133 can prevent fickleness in diagnostic routines resulting from transient, non-trending and non-significant fluctuations in the various collected and derived measures in favor of more certainty in diagnosis.")
- *retrieving only those trial data that meet the predefined criteria from the trial database*; (see at least Bardy [0011] "A plurality of monitoring sets is retrieved from a database. Each monitoring set includes recorded measures that each relates to patient information and include either medical device measures or derived measures calculable therefrom. The medical device measures are recorded on a substantially continuous basis. A set of indicator thresholds is defined.")

- *accessing a blinding database containing subject identifiers and an associated study group identifier for each subject, each study group identifier identifying to which study group each subject belongs;* (see at least Bardy [0037] "The device and derived measures sets 24a, 24b (shown in FIG. 1), along with quality of life and symptom measures sets 25a, 25b, as further described below with reference to FIG. 3, are continuously and periodically received by the server system 16 as part of the on-going patient care monitoring and analysis function. These regularly collected data sets are collectively categorized as the monitoring sets 27")
- *producing a grouped database from the retrieved trial data and the blinding database for statistical analysis, the grouped database grouping the trial data according to the study group*. (see at least Bardy Fig.5 Items:26,27,125,129-133)

Claim 8

The combination of Bardy/Pence discloses all the limitations of Claim 7. Pence further discloses the following limitation:

- *wherein the grouped database is stored in a memory device that is inaccessible by any user to preserve the blindness of the clinical trial*. (see at least Pence Column:5 Lines:47-51 "the unit history record mentioned above, a single record is stored in a database on disk 11 of FIG. 1 for each disk drive or device. There is keyed access to this record, based on the unique device serial number.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 7, as taught in Bardy/Pence *wherein the grouped database is stored in a memory device that is inaccessible by any user*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 9

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value*. (see at least Bardy Fig. 5 Item:127 and [0041] "the patient information stored in the database 17 is analyzed and compared to pre-determined cutoff levels, which, when exceeded, can provide etiological indications of congestive heart failure symptoms.")

Claim 10

The combination of Bardy/Pence discloses all the limitations of Claim 9. Pence further discloses the following limitation:

- *wherein the predetermined threshold value includes a predetermined statistical significance value* (see at least Pence Column:7 Lines:28-31 "Step 95 compares the Sigma calculation to statistically significant thresholds. The thresholds are previously determined as being significant by the user.")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 9, as taught in Bardy/Pence, *wherein the predetermined threshold value includes a predetermined statistical significance value*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 11

The combination of Bardy/Pence discloses all the limitations of Claim 10. Pence further discloses the following limitation:

- *retrieving a user defined statistical model; and running the retrieved user defined statistical model on the trial database*. (see at least Pence Column:7 Lines:28-31 "Step 95 compares

the Sigma calculation to statistically significant thresholds. The thresholds are previously determined as being significant by the user.")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 10, as taught in Bardy/Pence *retrieving a user defined statistical model; and running the retrieved user defined statistical model on the trial database.*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 12

Bardy as shown, discloses the following limitations:

- *accessing a trial database containing blinded trial data of subjects in an ongoing blinded clinical trial; - performing a statistical analysis on the produced grouped database*; (see at least Bardy [0009] "Select stored and derived measures are analyzed and changes in patient condition are logged. The logged changes are compared to quantified indicator thresholds to detect findings of respiratory distress or reduced exercise capacity indicative of the two principal cardiovascular pathophysiological manifestations of congestive heart failure: elevated left ventricular end diastolic pressure and reduced cardiac output, respectively.")
- *accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;* (see at least Bardy [0037] "The device and derived measures sets 24a, 24b (shown in FIG. 1), along with quality of life and symptom measures sets 25a, 25b, as further described below with reference to FIG. 3, are continuously and periodically received by the server system 16 as part of the on-going patient care monitoring and analysis function. These regularly collected data sets are collectively categorized as the monitoring sets 27")
- *producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;* (see at least Bardy Fig.5 Items:26,27,125,129-133)

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059] "A predicted measure value can be calculated and compared to the appropriate indicator threshold 129 for determining whether the particular measure has either exceeded an acceptable threshold rate of change or the absolute threshold limit.")

Bardy does not disclose the following limitation, however Pence, as shown does:

- *if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the above steps* (see at least Pence Fig. 2 Items:50, 52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine limitations above taught in Bardy, with *repeating the above steps, if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value,* as taught in Pence, with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system. (see at least Bardy [0008])

Claim 13

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis*; and(see at least Bardy [0048] "In addition, the feedback module 128 determines whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") 133, as further described below with reference to FIG. 16. The threshold stickiness 133 can prevent fickleness in diagnostic routines resulting from transient, non-trending and non-significant fluctuations in the various collected and derived measures in favor of more certainty in diagnosis.")
- *retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis*. (see at least Bardy [0011] "A plurality of monitoring sets is retrieved from

a database. Each monitoring set includes recorded measures that each relates to patient information and include either medical device measures or derived measures calculable therefrom. The medical device measures are recorded on a substantially continuous basis. A set of indicator thresholds is defined.")

Claim 14

The combination of Bardy/Pence discloses all the limitations of Claim 12. Pence further discloses the following limitations:

- *wherein the produced grouped database is stored in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51 "the unit history record mentioned above, a single record is stored in a database on disk 11 of FIG. 1 for each disk drive or device. There is keyed access to this record, based on the unique device serial number.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 12, as taught in Bardy/Pence *wherein the produced grouped database is stored in a memory device that is inaccessible by any user*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 15

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *wherein the step of performing a statistical analysis is executed without locking the trial database*. (see at least Bardy [0048] "the analysis module 131 analyzes the results from the comparison module 130, which are stored as a combined measures set 95 (not shown), to a set of indicator thresholds 129,")

Claim 16

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value*. (see at least Bardy Fig. 5 Item:127 and [0041] "the patient information stored in the database 17 is analyzed and compared to pre-determined cutoff levels, which, when exceeded, can provide etiological indications of congestive heart failure symptoms.")

Claim 17

The combination of Bardy/Pence discloses all the limitations of Claim 16. Pence further discloses the following limitations:

- *wherein the predetermined threshold value includes a predetermined statistical significance value*. (see at least Pence Column:7 Lines28-31 Step 95 compares the Sigma calculation to statistically significant thresholds. The thresholds are previously determined as being significant by the user.")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 16, as taught in Bardy/Pence, *wherein the predetermined threshold value includes a predetermined statistical significance value*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 18

Bardy as shown, discloses the following limitations:

- *a storage device operable to store a trial database containing trial data of subjects in an ongoing clinical trial*; (see at least Bardy [0035] The database 17 stores patient care records 23 for each individual patient to whom remote patient care is being provided . . . The patient care records 23 consist primarily of two sets of data: device and derived measures")
- *a processor coupled to the storage device*; (see at least Bardy Fig. 1 Items14,16-18)

- *an analysis program executable by the processor* (see at least Bardy Fig. 5 Items16,131)
- *operable to perform a statistical analysis on the trial database*; (see at least Bardy [0009] "Select stored and derived measures are analyzed and changes in patient condition are logged. The logged changes are compared to quantified indicator thresholds to detect findings of respiratory distress or reduced exercise capacity indicative of the two principal cardiovascular pathophysiological manifestations of congestive heart failure: elevated left ventricular end diastolic pressure and reduced cardiac output, respectively.")
- *determine whether the output result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy "A predicted measure value can be calculated and compared to the appropriate indicator threshold 129 for determining whether the particular measure has either exceeded an acceptable threshold rate of change or the absolute threshold limit.")

Bardy does not disclose the following limitation, however Pence, as shown does:

- *repeat the statistical analysis while the clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value*. (see at least Pence Fig. 2 Items:50, 52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine *a storage device operable to store a trial database containing trial data of subjects in an ongoing clinical trial*, *a processor coupled to the storage device*, *an analysis program executable by the processor*, *operable to perform a statistical analysis on the trial database,* and *determine whether the output result of the statistical analysis exceeds a predetermined threshold value* as taught in Bardy, with the *repeat the statistical analysis while the clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value*, as taught in Pence, with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system. (see at least Bardy [0008])

Claim 19

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitations:

- *read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis*; (see at least Bardy [0048] "the analysis module 131 analyzes the results from the comparison module 130, which are stored as a combined measures set 95 (not shown), to a set of indicator thresholds 129,")
- *retrieve only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011] "A plurality of monitoring sets is retrieved from a database. Each monitoring set includes recorded measures that each relates to patient information and include either medical device measures or derived measures calculable therefrom. The medical device measures are recorded on a substantially continuous basis. A set of indicator thresholds is defined.")

Claim 20

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further discloses the following limitations:

- *wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis*. (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 18, as taught in Bardy/Pence *wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis*, as taught in Pence, with the motivation of providing a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 21

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *produce a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data according to the study group.* (see at least Bardy Fig.5 Items:26,27,125,129-133)
- *access a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;* (see at least Bardy [0037] "The device and derived measures sets 24a, 24b (shown in FIG. 1), along with quality of life and symptom measures sets 25a, 25b, as further described below with reference to FIG. 3, are continuously and periodically received by the server system 16 as part of the on-going patient care monitoring and analysis function. These regularly collected data sets are collectively categorized as the monitoring sets 27")

Claim 22

The combination of Bardy/Pence discloses all the limitations of Claim 21. Pence further discloses the following limitation:

- *a memory device coupled to the processor* (see at least Pence Fig. 1 Items:11,15 and related text).
- *being inaccessible to any user, wherein the grouped database is stored only in the memory device*. (see at least Pence Column:5 Lines:47-51 "the unit history record mentioned above, a single record is stored in a database on disk 11 of FIG. 1 for each disk drive or device. There is keyed access to this record, based on the unique device serial number.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine all the limitations Claim 21, as taught in Bardy/Pence, with *a memory device coupled to the processor* and *being inaccessible to any user, wherein the grouped database is stored only in the memory device*, as taught in Pence, with the motivation of providing a more efficient approach for

continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 23

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program performs the statistical analysis without locking the trial database* (see at least Bardy [0048] "the analysis module 131 analyzes the results from the comparison module 130, which are stored as a combined measures set 95 (not shown), to a set of indicator thresholds 129,")

Claim 24

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value* (see at least Bardy "A predicted measure value can be calculated and compared to the appropriate indicator threshold 129 for determining whether the particular measure has either exceeded an acceptable threshold rate of change or the absolute threshold limit.")

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **571-270-3930.** The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **James A. Reagan** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair <http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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Date: 02/14/08
/Rajiv J Raj/ Patent Examiner Art Unit 4143
/James A. Reagan/Supervisory Patent Examiner, Art Unit 4143